



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,475	08/12/2002	Joshua W Hamilton	DC-0190	1040
26259	7590	08/11/2005	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			MURPHY, JOSEPH F	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,475

Applicant(s)

HAMILTON ET AL.

Examiner

Joseph F. Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Art Unit: 1646

DETAILED ACTION

Formal Matters

Claim 9 is pending and under consideration.

Response to Arguments

The rejection of Claim 9 under 35 U.S.C. 103(a) as being unpatentable over Moyer et al. (1999) in view of Cormack et al. (1996), has been withdrawn based on Applicant's arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moyer et al. (1999) in view of Cormack et al. (1996), further in view of Chou et al. (1991).

Art Unit: 1646

The rejection of record set forth that Moyer (Moyer BD, Loffing-Cueni D, Loffing J, Reynolds D, Stanton BA. Butyrate increases apical membrane CFTR but reduces chloride secretion in MDCK cells. *Am J Physiol.* 1999 Aug; 277(2 Pt 2): F271-6) teaches a method of measuring the effect of butyrate on the expression of a CFTR-GFP nucleic acid. The construct comprising CFTR-GFP is set forth on page F272, column 2, third paragraph. The method is set forth on page F274 Figure 3. The Moyer et al. reference teaches the use of CFTR with the deltaF-508 mutation in the method of measuring the effect of butyrate on the expression of a CFTR-GFP nucleic acid which they disclose. This meets the limitations of the claims that the CFTR is a "mutant" CFTR. Moyer et al. does not teach the method using a nucleic acid construct comprising CFTR and eGFP. Cormack et al. (Cormack BP, Valdivia RH, Falkow S. FACS-optimized mutants of the green fluorescent protein (GFP). *Gene.* 1996; 173(1 Spec No): 33-8) teaches the cloning of GFP mutants which fluoresce more intensely than wild type GFP (page 35, Figure 2). Neither the Moyer nor Cormack references teach the use of the proximal human CFTR promoter. The Chou reference teaches the transcription regulatory elements of the cystic fibrosis transmembrane conductance regulator (CFTR) gene, and that one was a proximal, positive element delimited by the 5' deletion constructs -226 base parts upstream of the transcription start site (page 24473, Figure 2). Therefore, it would have been obvious to one of skill in the art at the time the invention was made to practice a method for identifying agents which increase functional cell surface expression of the deltaF508 CFTR protein by exposing cells comprising a genetic construct comprising human CFTR coding sequence and an reporter gene to the agent, measuring expression levels or trafficking of CFTR to the membrane, and comparing the levels of CFTR expression or tracking to controls as taught in the Moyer

Art Unit: 1646

reference, wherein the reporter gene is eGFP as taught in the Cormack reference, and the promoter used is the CFTR promoter as taught by Chou et al. The motivation is provided in the Cormack reference that teaches that eGFP has a greatly increased fluorescence intensity, making the mutants useful for a number of applications (page 37, column 2, second paragraph), and the Chou reference which teaches that the promoter of the CFTR can be used to obtain insights into the mechanisms governing the regulation of CFTR expression (page 24475, column 1, fourth paragraph).

Conclusion

Claim 9 is rejected.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.
Primary Examiner
Art Unit 1646
August 1, 2005



JOSEPH MURPHY
PATENT EXAMINER